

I. CLAIM LISTING

1-20 Cancelled

21) A process for (1) separating a target biological ligand known to be, or suspected of being, present in dilute concentration in an aqueous fluid and (2) determining the amount of said target ligand so separated, which process comprising the steps of

(a) coating with a first biological binding partner for said target biological ligand a group of superparamagnetic particles, which particles have an average mean diameter of at least about 100 nm and are each composed of discrete subunits of superparamagnetic material, which subunits have an average mean diameter of 1-30 nm and are separately spaced apart from one another within a covering matrix of non-metallic, non-magnetic material that is compatible with, but non-reactive with, said biological ligand and its first biological binding partner,

(b) immersing the coated superparamagnetic particles from step (a) in a sample of said aqueous fluid which is known to contain, or is suspected of containing, said target biological ligand and allowing said particles and said fluid to incubate for a time sufficient to enable the target biological ligand, if present, to react with its first biological binding partner coated on said particles, thereby forming complexes,

(c) exposing said complexes to the gradient of a magnetic field whereby the complexes acquire a magnetic charge and are attracted toward one another and away from the bulk of said fluid,

(d) removing said fluid from said complexes by any suitable means,

(e) washing said complexes and adding them to a small volume of an aqueous buffer to form a dispersion of said complexes in said buffer,

(f) applying said dispersion to the sample receiving end of an immunochromatographic (“ICT”) device configured as a dipstick and comprising a strip of bibulous material having at least one immovable stripe of a second binding partner for said target biological ligand which has been previously permanently affixed thereto at the end thereof remote from said sample receiving end,

(g) allowing said dispersion to migrate along said strip of bibulous material and contact said at least one immovable stripe of a second binding partner for said biological ligand, whereby said target biological ligand on the surface of said complexes binds to its second binding partner on said at least one immovable stripe,

h) measuring the magnetic charge intensity of said at least one immovable stripe, and

i) determining from a previously established standard curve, obtained by constructing a plot of measurements of magnetic charge intensity against amount of biological ligand present, obtained when a series of standardized samples each containing a different known amount of the target biological ligand were tested in the foregoing process, the amount of biological ligand present in the fluid sample.

22. A process according to claim 21 in which said aqueous fluid is of environmental origin.

23. A process according to claim 21 in which said aqueous fluid is of mammalian origin.

24. A process according to claim 23 in which said aqueous fluid is urine.

25. A process according to claim 21 in which said first biological binding partner and said second biological binding partner have the same composition.

26. A process according to claim 21 in which said first biological binding partner and said second biological binding partner are of different composition from one another.

27. A process according to claim 21 in which the discrete subunits having an average diameter of 1-30 nm of the superparamagnetic particles subjected to coating in step (a) are discrete particles of ferrofluid and the covering matrix of nonmetallic, nonmagnetic material by which they are separately spaced apart from one another is bovine serum albumen.

28. A process according to claim 21 in which the ICT device of step (f) comprises a strip of bibulous material having multiple immovable stripes, arranged in parallel spaced apart relationship from one another, of said second binding partner for the target biological ligand are permanently affixed thereto at the end of said strip remote from its sample receiving end;

in step (g) said dispersion migrates along said strip of bibulous material and is allowed to contact each of said multiple immovable stripes of said second binding partner for said target biological ligand, whereby some portion of said target biological ligand on the surface of said complexes in the sample reacts with said second binding partner immobilized on each of said stripes and the complexes are thereby concentrated along each said stripe;

in step (h) the magnetic charge intensity of each immobilized stripe is measured and the measured magnetic intensities of each of the immovable stripes are added to obtain a total value; and

in step (j) the total measured magnetic charge intensity of all the stripes is correlated, using said previously established standard curve, to the total amount of target biological ligand in the fluid sample.

29. A process according to claim 28 in which the aqueous fluid is of environmental origin.

30. A process according to claim 28 in which the aqueous fluid is of mammalian origin.
31. A process according to claim 30 in which the aqueous fluid is urine.
32. A process according to claim 28 in which said first biological binding partner and said second biological binding partner have the same composition.
33. A process according to claim 28 in which said first biological binding partner and said second biological binding partner are of different composition from one another.
34. A process according to claim 28 in which the discrete subunits having an average diameter of 1-30 nm of the superparamagnetic particles subjected to coating in step (a) are discrete particles of ferrofluid and the covering matrix of nonmetallic, nonmagnetic material by which they are separately spaced apart from one another is bovine serum albumen.